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| 10/594,037 | 09/25/2006 | Hirobumi Aoki | Q80830 | 8966 |

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| EXAMINER | |
|---|---|
| FISHER, ABIGAIL L | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/594,037 | AOKI ET AL. | |
| | Examiner | Art Unit | |
| | ABIGAIL FISHER | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/25/06, 3/14/07, 9/19/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-15 are pending.

### *Information Disclosure Statement*

The information disclosure statements (IDS) submitted on 9/25/06, 3/14/07 and 9/19/07 were considered by the examiner.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.**

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such as saccharides which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claim(s) 1 is(are) directed to encompass derivatives, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these (derivatives, analogs) meet the written description provision of 35 USC § 112, first

paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim. **Note: MPEP 2163.**

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004), further supports this by stating that:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Circ. 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016, (Fed. Cir. 1991). In Fiddes v. Baird, 30 USPQ2d 1481, 1483, (Bd. Pat. App. & Int. 1993), claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 (Fed. Cir. 1997) held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.

> 1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing "sufficiently detailed, relevant identifying characteristics," including "functional characteristics when coupled with a known or disclosed correlation between function and structure." Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003).

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 1 as currently written can be interpreted in two different ways. One interpretation is wherein the inositol is in the same preparation with a saccharide. The other interpretation is where the inositol is physically attached to the saccharide. A claim is indefinite wherein more than one interpretation exist for the claim. This dual interpretation is a result of the inconsistency in the way the claim is written by reciting that the preparation comprising "an inositol derivative in which an inositol is **combined** with a saccharide". The presence of the language "in which" and "combined" leads to the dual interpretation. Art will be applied to both interpretations of the claim.

Claim 3 recites that the monosaccharide and/or the oligosaccharide contains glucose as a "constitutional" unit. The term "constitutional" renders the claim indefinite because it is unclear what constitutional in this claim means. Does it mean that the monosaccharide and/or oligosaccharide is made up of only glucose? The examiner can find no definition of constitutional in the specification and the definitions of constitutional in the dictionary indicate that constitutional refers to of or pertaining to the constitution of a state, organization, or character or makeup of a person's body or mind. It is unclear how that would apply in this claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-3, 5-6, 9-10, 12-13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Jain (US PG PUB No. 2003/0068297).**

Applicants claim an external preparation for skin comprising an inositol derivative in which an inositol is combined with a saccharide. A specific saccharide claimed is glucose. The claimed amount of the inositol and saccharide is from 0.01 to 50% by mass of the preparation. Additionally claimed is a cosmetic comprising the external preparation above.

Jain is directed to compositions and methods for skin rejuvenation and repair. Examples 1-3 are directed to compositions that rejuvenate the skin and improve the texture of the skin and provide for skin repair. It comprises as a sugar D-glucose and vitamins. Examples of the vitamins are B12, choline chloride and inositol. The amount of D-glucose taught is 0.2 to 0.6 % (2 to 6 g/L) and inositol is 0.0005 to 0.0015 % (0.5 to 15 mg/L), which taken together are from 0.2005 to 0.6015 %. The MPEP indicates that "anticipation can only be found if the classes of substituents are sufficient limited or well delineated" and that "if one of ordinary skill in the art is able to 'at once envisage' the specific compound within a generic chemical formula, the compound is anticipated. **Note MPEP 2131.02.** Therefore, since there are only three different vitamins taught in

the examples, one of ordinary skill in the art is able to immediately envision a composition comprising the inositol.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 4, 7-8, 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain in view of Minami et al. (JP-10-114614, cited on PTO Form 1449).**

**Applicant Claims**

Applicants claim that the inositol claimed is myo-inositol.

**Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

Jain is directed to compositions and methods for skin rejuvenation and repair. Example 1-3 are directed to compositions that rejuvenate the skin and improve the texture of the skin and provide for skin repair. It comprises as a sugar D-glucose and vitamins. Examples of the vitamins are B12, choline chloride and inositol. The amount of D-glucose taught is 0.2 to 0.6 % (2 to 6 g/L) and inositol is 0.0005 to 0.0015 % (0.5 to 15 mg/L), which taken together are from 0.2005 to 0.6015 %.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)***

Jain does not specify that the inositol is myo-inositol. However, this deficiency is cured by Minami et al.

Minami et al. (utilizing the machine translated document) teach that nine steroisomeric forms of inositol exist. They prefer using the naturally occurring type which is myo-inositol (paragraph 0011). The compositions is directed to cosmetics (paragraph 0010).

***Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Jain and Minami et al. and utilize inositol in the form of myo-inositol. One of ordinary skill in the art would have been motivated to utilize myo-inositol because it is taught by Minami et al. as being a naturally occurring stereoisomer form of inositol. Furthermore, there are only nine different stereoisomer of inositol, and it would have been obvious to one of ordinary skill in the art to try every stereoisomer as a person with ordinary skill has good reason to pursue known options within his or her technical grasp. **Note: MPEP 2141 [R-6]** *KSR International CO. v. Teleflex Inc.* 82 USPQ 2d 1385 (Supreme Court 2007). Finally, one of ordinary skill in the art would have a reasonable expectation of success as Minami et al. indicate that the myo-inositol is utilized in cosmetic formulations, therefore, there is a reasonable expectation that it can be utilized in cosmetic formulations designed to improve the skin.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

**Claims 1-3, 5 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sleevi et al. (US Patent No. 6492339).**

**Applicant Claims**

Applicants claim an external preparation for skin comprising an inositol derivative in which an inositol is combined with a saccharide. A specific saccharide claimed is

glucose. The claimed amount of the inositol derivative is from 0.01 to 50% by mass of the preparation. Additionally claimed is a cosmetic comprising the external preparation above.

**Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

Sleevi et al. is directed to compositions comprising D-chiro inositol. It is taught that the term D-chiro-inositol includes the inositol, derivatives thereof, or compounds containing D-chiro inositol. Examples include polysaccharides containing D-chiro-inositol and one or more additional sugars such as glucose, galactose, and mannose (column 4, lines 20-45). Formulations of the invention are suitable for administration in oral, nasal, topical, rectal, vaginal and or parenteral form (column 8, lines 29-32). Dosage forms for topical or transdermal administration include powders, sprays, ointments, pastes, creams, lotions, gels, solutions, patches and inhalants (columns 9-10, lines 66-67 and 1-5). The active ingredients can be incorporated in amount from 0.01 to 99.5% (column 10, lines 47-52).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)***

Sleevi et al. do not exemplify a topical formulation comprising polysaccharides containing D-chiro-inositol. However, Sleevi et al. do teach that topical is one suitable dosage form that the polysaccharides containing D-chiro-inositol are one suitable form of the inositol.

***Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize polysaccharides containing D-chiro-inositol such as polysaccharides containing D-chiro-inositol and glucose. One of ordinary skill in the art would have been motivated to utilize polysaccharides containing D-chiro-inositol and glucose as Sleevi et al. teach that suitable compounds containing D-chiro-inositol include polysaccharides. It would have been obvious to one of ordinary skill in the art to try the different D-chiro-inositol compounds taught by Sleevi et al. as a person with ordinary skill has good reason to pursue known options within his or her technical grasp. **Note: MPEP 2141 [R-6]** *KSR International CO. v. Teleflex Inc.* 82 USPQ 2d 1385 (Supreme Court 2007).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize polysaccharides containing D-chiro-inositol such as polysaccharides containing D-chiro-inositol and glucose in a topical formulation. One of ordinary skill in the art would have been motivated to formulate a topical dosage formulation as Sleevi et al. specifically teach that this is one suitable formulation for the delivery of D-chiro-inositol containing compounds. It would have been obvious to one of ordinary skill in the art to formulate D-chiro-inositol into different dosage forms depending on the desired end use.

Regarding the claimed amount of inositol derivative, Sleevi et al. teach an amount that overlaps that instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. **See MPEP 2144.05 [R-5]**

**Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamothe et al. (US Patent No. 5518733) in view of Satou (JP Patent No. 63196596, English Translation submitted).**

**Applicant Claims**

Applicants claim an external preparation for skin comprising an inositol derivative in which an inositol is combined with a saccharide. A specific saccharide claimed is glucose. A specific the inositol claimed is myo-inositol. The claimed amount of the inositol and saccharide is from 0.01 to 50% by mass of the preparation. Additionally claimed is a cosmetic comprising the external preparation above.

**Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

Lamothe et al. is directed to cosmetic compositions containing oligosaccharides. Lamothe et al. teach cosmetics which create a medium favorable for the development of beneficial endogenous flora. It was found that oligosaccharides of the invention were metabolized in the presence of certain strains such as Lactobacillus pentosus, which produces lactic acid, and acidified culture medium. However, pathogenic strains such as staphylococcus aureus do not metabolize or very slightly metabolize the oligosaccharides (column 1, lines 17-36). The oligosaccharides taught include gluco-oligosaccharides, fructo-oligosaccharides and galacto-oligosaccharides (column 1, lines 43-47). The amount of oligosaccharide present in the cosmetic is from 0.1 to 20% (column 2, lines 63-65). Exemplified are various different cosmetic formulations (soap, shampoo, face cream and vaginal gel) comprising the oligosaccharides.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)***

Lamothe et al. do not teach that the oligosaccharide comprises myo-inositol. However, this deficiency is cured by Satou et al.

Satou et al. is directed to the formation of gluco-oligosaccharides and attaching an inositol residue in the end. The gluco-oligosaccharide has the general formula of $(Glc)_n$-(Glc)-Ino wherein Glc represents glucose and Ino represent inositol (claim 1). The inositol as claimed is myo-inositol. It is general taught that oligosaccharides are known in the art as biochemical reagents for amylase activity measurements, low-dental caries inducing sweeteners, and growth-promoting substances for bifidobacterium (page 3, related art). The oligosaccharides of Satou et al. comprising inositol are useful as growth-promoting substances for Bifidobacterium (pages 4-5 and 19, objective of the invention and Table 1).

***Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Lamothe et al. and Satou et al. and utilize gluco-oligosaccharides comprising inositol in the cosmetic of Lamothe et al. One of ordinary skill in the art would have been motivated to utilize these gluco-oligosaccharides because Lamothe et al. teach the formation of cosmetic compositions comprising gluco-oligosaccharides that create a medium favorable for the development of beneficial endogenous flora such as by generating lactic acid and Satou et al. teach gluco-oligosaccharides that promote the growth of a lactic acid generating

bifidobacterium. Since both Lamothe et al. and Satou et al. teach oligosaccharides that promote the growth of beneficial endogenous flora one of ordinary skill in the art would have a reasonable expectation of success of utilizing the gluco-oligosaccharides of Satou et al. in the cosmetic formulation of Lamothe et al.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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AF

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